Amendments to the Specification:

Please replace paragraph 1 on page numbered 2 with the following amended paragraph:

--This application is a continuation of ~~application Serial~~ Application No. 08/480,904, filed June 7, 1995, now U.S. Patent No. 6,210,412. ~~This application is also a continuation in part of design patent Application Serial No. 29/023,623 entitled Spinal Distractor filed on October 3, 1994.--~~

Please replace paragraph 1 on page numbered 3 with the following amended paragraph:

-- Michelson, in U.S. patent application Ser. No. 08/396,414, now U.S. Patent No. 6,080,155, entitled ~~APPARATUS AND~~ METHOD OF INSERTING AND PRELOADING SPINAL IMPLANTS, teaches a method for restoring the anatomical lordosis of the spine while performing the interbody fusion procedure. While this has been a significant advance over prior methods, it has nevertheless been associated with a sometimes less than desirable consequence, that being the uneven removal of bone from each of the adjacent vertebrae relative to the vertebral endplates adjacent the disc space.--

Please add the following paragraphs after paragraph 7 on page numbered 9:

--Figure 16 is a side elevational view of a long distractor inserted into an intervertebral space.

Figure 17 is a side elevational view of a convertible long distractor including a short distractor positioned in the intervertebral space.

Figure 18 is a perspective view of the short distractor shown in Figure 17.

Figure 18A is a side elevational view of the short distractor shown Figures 17 and 18.

Figure 18B is a side elevational view of an alternative short distractor with circumferential forward facing ratchetings.

Figure 18C is a top view of the alternative short distractor of Figure 18B.

Figure 18D is a perspective view of an another alternative short distractor.

Figure 18E is a top view of the alternative short distractor of Figure 18D.

Figure 18F is a side elevational view of a further alternative short distractor having knurled surfaces.

Figure 19 is a perspective view of a spinal segment (two vertebrae and an interposed disc) with a short distractor in place, with a portion of the upper vertebrae and disc cut away to show the short distractor on one side of the spine and a long distractor about to be placed contralaterally.

Figure 20 is a perspective view of an anterior lordotic extended outer sleeve having extended members for restoring and maintaining lordosis of the spine from the anterior aspect of the spine.

Figure 21 is a perspective view of a dual extended outer sleeve having an extension that decreases in height in the direction of insertion.

Figure 22 is a front elevational view of the dual extended outer sleeve shown in Figure 21.

Figure 23 is a perspective view of a dual extended outer sleeve having two extensions that decrease in height in the direction insertion.

Figure 24 is top plan view of a dual extended outer sleeve for use in installing interbody spinal implants having one or more flat sides, shown placed over two long distractors with the prongs inserted into a vertebrae.

Figure 25 is a front elevational view of the dual extended outer sleeve shown in Figure 24.

Figure 26 is a rear elevational view of the dual extended outer sleeve of Fig. 24 positioned relative a disc space to receive a drill therein.

Please replace the paragraph bridges pages numbered 19 and 20 with the following amended paragraphs:

--In the preferred embodiment, the diseased disc is first removed by conventional discectomy. The depth of the disc space is then determined by

direct measurement. An interspace distractor such as that described by Michelson in U.S. ~~patent application Ser. No. 08/396,414~~ Patent No. 6,080,155, ~~entitled Apparatus and Method of Inserting Spinal Implants~~, incorporated herein by reference, is then inserted into the disc space. A series of such distractors are available and are sequentially inserted until the optimal amount of distraction across the disc space is achieved. The interspace distractors utilized for this purpose are wedged so as to induce physiological lordosis.

For example, referring now to Figure 16, preferably after removing some portion of nuclear disc material, a disc penetrating portion 1002 of a long distractor 1000 is inserted under direct vision into the intervertebral (or disc) space and disc D' between the vertebral bodies V'. The penetrating portion 1002 is essentially cylindrical with a bullet-shaped front end 1004 and a shoulder portion 1006 where the penetrating portion 1002 extends from barrel 1008. The penetrating portion 1002 urges the vertebral bodies apart, facilitating the introduction of the instruments. Long distractors with sequentially increasing diameter penetrating portions 1002 are then introduced. As the optimal diameter of penetrating portion 1002 is achieved, the vertebrae V' to either side are forced into full congruence and thus become parallel, not only to the penetrating portion 1002, but to each other.

Referring to Figure 17, in the preferred embodiment, a convertible long distractor 1010 is used on the first side of the spine. The convertible long distractor 1010 has a barrel portion 1012 separable from a short distractor 1014. While the initial distraction may be performed with a solid long distractor, as the optimal distraction is approached the appropriate convertible long distractor is utilized. The barrel portion 1012 includes a rectangular projection (or male mating member) 1016 at one end, and the short distractor 1014 has an increased diameter head 1018, a female rectangular slot 1020 and an internal threaded opening 1022.

The short distractor 1014 is removably attached to the barrel portion 1012 via the mating of female rectangular slot 1020 and the male mating member

1016. The mating of the female rectangular slot 1020 and the male mating member 1016 is held together by threading a threaded working end screw 1024 of an interior shaft 1026 extending through the barrel portion 1012 into the female rectangular slot 1020. The threaded working end screw 1024 corresponds to the internal threaded opening 1022. A knob 1028 serves to drive a crown 1030 connected to the interior shaft 1026. The knob 1028 has a open socket 1032 for fitting around the crown 1030, and engages a reduced diameter hexagonal portion 1034 of the crown 1030 to rotate the interior shaft 1026 and the threaded working end screw 1024. A detent ball 1036 on the inside of the open socket 1032 engages a detent 1037 in the crown 1030 to hold the knob 1028 and the crown 1030 together.

Referring to Figures 17, 18, and 18A-18F the short distractor 1014 shown therein are designed to provide for high stability when temporarily situated so as to resist inadvertent migration while the surgeon is working on the second side. To that end, the embodiment of the short distractor 1014 shown in Figures 17, 18, and 18A, has a pair of sharp pegs (or prongs) 1038, to embed into the opposing vertebral bodies and forward facing ratchetings 1039, that further resist backward movement. Figures 18B and 18C are side and top views of an alternative embodiment of the short distractor 1014 such that the distractor portion to be interposed between the vertebrae is essentially cylindrical, but with circumferential forward facing ratchetings 1039. Referring to Figures 18D and 18E, another alternative embodiment of the short distractor 1014 is shown having a more rectangularized design, with forward facing ratchetings, without the sharp prongs 1038 of Figures 17, 18, and 18A. Figure 18F is a side view of a further alternative embodiment of the short distractor 1014 shown with knurling, to increase the interference with the bone surface so as to add stability to the unit and to resist dislodgment. To this end, it is apparent that the working ends of both the long and short distractors can have a variety of configurations consistent with their purpose, and that surface irregularities as well as the shape of the ends themselves, with or without prongs 1038, may be utilized to make the

short distractor 1014 more resistant to migration.

Once the ideal distraction has been achieved on the first side of the spine, the convertible distractor 1010 is dissociated, leaving the short distractor 1014 in place. Referring to Figure 19, the surgeon then moves to the other side of the spine at the same disc ~~(D)~~level, and retracts the dural sac and nerve root medially, exposing the disc on that side. Long distractors 1000 are then sequentially inserted into the disc space until the diameter of the distractor on the second side is at least as big as that on the first side. Although use of long distractor 1000 and convertible distractor 1010 are shown in Figures 16, 17, and 18 being used posteriorly, similar devices can be used anteriorly.

An outer sleeve is then fitted over the barrel portion of the interspace distractor barrel 1008 of long distractor 1000 or barrel 1012 of convertible distractor 1010 and firmly seated in engagement with the spine. As discussed below and previously described in U.S. ~~patent application Ser. No. 08/396,414~~ Patent No. 6,080,155, ~~said~~ the outer sleeve may itself have extended portions capable of either maintaining or of obtaining and maintaining distraction. ~~Said~~ The outer sleeve may also have vertebrae engaging prongs to further stabilize the outer sleeve to the spine and to more rigidly control motion at the adjacent vertebrae. As discussed below and described in U.S. ~~patent application Ser. No. 08/396,414~~Patent No. 6,080,155, the use of the extended outer sleeve with distractor portions actually makes it possible to achieve the optimal distraction and lordosis without the use of the described interspace distractor. A number of different embodiments of outer sleeves are discussed below. However, if the interspace distractor is used, then the outer sleeve is fully engaged to the spine, the distractor is removed, and in the preferred method by use of a slap-hammer, engaging the most proximal aspect of the distractor.

For example, referring to Figure 20, an anterior extended outer sleeve 1040 for use from the anterior approach of the spine is shown. The anterior extended outer sleeve 1040 comprises a hollow tubular member 1042 having a distal end 1044 which has been extended such that a pair of extended portions

1046 and 1048 which are essentially a continuation of the tubular member 1042 and are opposed 180 degrees from each other. The extended portions 1046 and 1048 are configured to restore and maintain lordosis of the spine from the anterior approach. The extended portions 1046 and 1048 each have a height that is greater at a point proximate to the distal end 1044 of the tubular member 1042 that decreases in the direction away from the tubular member 1042. The extended portions 1046 and 1048 are tapered at their leading edges 1050 and 1052, respectively, to facilitate insertion into the disc space.

While the anterior extended outer sleeve 1040 for use anteriorly is shown in the singular form and in use in the lumbar spine, it is understood that it may take a double barrelled form and in either form, be used throughout the spine. For example, referring to Figures 21 and 22, a dual extended outer sleeve is shown and generally referred to by the numeral 1060. The dual extended outer sleeve 1060 comprises two hollow tubular members 1062 and 1064. The two hollow tubular members 1062 and 1064 have a distal end 1066 which has been extended to form an extended portion 1068 which is essentially a continuation of the hollow tubular members 1062 and 1064 joined together. The extended portion 1068 is similar in shape and function to the extended portions 1046 and 1048 described above in reference to Figure 20. The extended portion 1068 has a height that is greater at a point proximate the distal end 1066 and decreases in the direction away from the hollow members 1062 and 1064, in order to maintain the normal curvature of the spine by correcting the angular relationships of the vertebrae V'. The extended portion 1068, is tapered at its leading edge 1070 to facilitate insertion of the extended portion 1068 into the disc space between two adjacent vertebrae V'. Located at the distal end of the tubular members 1062 and 1064 are sharpened teeth 1072 for engaging the vertebrae V'. The tubular members 1062 and 1064 may be bridged in part or wholly throughout their length, but are typically fixed by a foot plate 1074. Referring specifically to Figure 22, the foot plate 1074 has an oval configuration that contours and hugs the vertebrae V' and has a plurality of prongs 1076A-1076D extending from the

foot plate 1074 is shown. The prongs 1076A-1076D are sufficiently long to engage the bone of adjacent vertebrae V', but limited in length so as not to over penetrate beyond the vertebrae once inserted.

Referring to Figure 23, another dual extended outer sleeve 1080 having two hollow tubular members 1082 and 1084 is shown. The dual extended outer sleeve 1080 is similar to the dual extended outer sleeve 1060, except that it has additional extended portions 1086, 1087 and 1088 which have a height that is greater near the distal end 1090 of the hollow tubular members 1082 and 1084 and decreases in the direction away from the hollow tubular members 1082 and 1084. The extended portions 1086, 1087 and 1088 are similar in shape and function to the extended portions 1046 and 1048 described above in reference to Figure 20. A foot plate 1092 is also provided. As the foot plate 1092 is rectangular and larger than foot plate 1074, prongs 1094E and 1094F, in addition to prongs 1094-1094D, may be added.--

Please replace paragraph 1 on page numbered 20 with the following amended paragraph:

-- Referring to FIG. 13, a segment of the spinal column S is shown with vertebrae V_1 and V_2 shown in lordosis adjacent to disc space D_1 and vertebrae V_2 and V_3 shown not in lordosis, but relatively parallel to each other adjacent disc space D_2. A first drill 810 making an opening 812 across the disc space D_1, and into adjacent vertebrae V_1 and V_2, and a second drill 820 making an opening 822 across the disc space D_2 and into adjacent vertebrae V_2 and V_3 are shown in FIG. 13. In the preferred embodiment, the interbody spinal fusion implant itself is threaded and frusto-conical in shape and therefore, the remaining portion of the procedure will be described in regard to that particular embodiment of the present invention, by way of example. With the disc space fully distracted and in anatomical lordosis and with the outer sleeve firmly engaged to the spine, it is then desirable to prepare the spine for receipt of the interbody fusion implant. It is preferable to prepare a space across the disc space and penetrating into the

adjacent vertebrae which space corresponds roughly to the root dimensions of the implant to be implanted. For this purpose, a stopped-out bone cutting instrument is inserted through the outer sleeve, the shape of the cutting portion of the first drill ~~510~~ 810 generally corresponding to the frusto-conical shape of the root diameter of the implant being inserted. This instrument may take the form of a frusto-conical drill or a mill and may be used to cut the bone by rotation, said rotation being achieved either through a manual handle or with power. Having prepared the space, the surgeon has two options. One is to remove the outer sleeve and then, because the implant is itself frusto-conical, screw the implant in using an implant driver capable of locking to the implant. The other is to leave the outer sleeve in place during the insertion of the implant.--

Please replace the paragraph bridges pages numbered 21 and 22 with the following amended paragraphs:

--The approach to the lumbar spine may either be retroperitoneal, or transperitoneal. The procedure may be performed under direct vision, or laproscopically with the use of an endoscope. Generally it is preferable to utilize two implants which are inserted in an anterior to posterior direction, one to either side of the midline. The implants may be inserted using either a single-barrelled or double-barrelled outer sleeve as described above, and by the methods previously described in ~~the pending~~ U.S. ~~patent application Ser. No. 08/396,414~~ Patent No. 6,080,155 from which the present methods differ only in the shape of the drill end or bone milling device which is essentially conical. As also previously described, in ~~copending application Ser. No. 08/396,414~~U.S. Patent No. 6,080,155, the methods can be utilized for the insertion of non-threaded implants (such as implants 222') in which case ~~said~~ the implants are linearly advanced rather than threaded in. And finally, as previously described in ~~co-pending~~U.S. application Ser. No. 08/390,131, now U.S. Patent No. 5,593,409, the implants themselves may have truncations on the sides to form a planar

surface parallel to the longitudinal axis of the implant, such that it is possible to fit two such implants more closely together by narrowing the width of each while preserving their height. As taught in ~~copending application Ser. No. 08/396,414~~U.S. Patent No. 6,080,155, a tap may be used after the drilling step and prior to the insertion of the implants.

For example, when implants having truncated sides, such as two implants 220' shown in Figures 6A and 6B, a dual outer sleeve 1100 having a pair of overlapping, hollow cylindrical tubes 1102 and 1104 can be utilized as shown in Figs. 24-26. The cylindrical tubes 1102 and 1104 are identical in size and each has an internal diameter slightly larger than the outer diameter of the spinal fusion implant to be inserted therethrough. The cylindrical tubes 1102 and 1104 are in communication with each other along their length and are displaced from each other ideally a distance that is slightly greater than the sum of the diameters of two spinal fusion implants 220' placed side-by-side with the flat sides 270 of each of the spinal fusion implants touching. The cylindrical tubes 1102 and 1104 are joined longitudinally such that they are partially overlapping. The cylindrical tubes 1102 and 1104 are mounted on a foot plate 1106 similar to the foot plate 1092 shown in Figure 23. There are a series of prongs 1108A-1108F projecting from the foot plate 1106 which are used to engage the dual outer sleeve 1100 to the base of the adjacent vertebrae V'.

Referring specifically to Figure 24, the dual outer sleeve 1100 is introduced over two long distractors 1110 and 1112 placed side-by-side and protruding anteriorly from the vertebrae V'. The long distractors 1110 and 1112 are similar to the long distractor 1000 described above except that they have a flat side 1114 and 1116, respectively.

As shown in FIGS. 24, the foot plate 1106 is contoured so as to approximate the external curvature of the vertebrae V' anteriorly. The sharp prongs 1108A-1108F are sufficiently long to permit fixation of the foot plate 1106, but are limited in length so as to not penetrate the vertebrae V' too far posteriorly and number from 2 to 10, but preferably 6. Once the dual outer sleeve 110 has

been fully seated, the vertebrae V' adjacent the disc space to be fused are rigidly held via foot plate 1106 and the prongs 1108A-1108F. Thus, it is possible to remove either one, or if desired, both of the long distractors 1110 and 1112. The dual outer sleeve has been described above for inserting two implants each having at least one flat side, and may have extended portions for insertion into the disc space which are capable of producing distraction as well as lordosis as previously described with such extensions extending in line with the lateral walls of the cylindrical tubes.

Referring to FIG. 26, once the dual outer sleeve 1100 has been fully seated, one of the long distractors 1110 and 1112 is removed and the surgeon may drill the disc space D' between the vertebrae V' utilizing drill 1120 using each of the hollow cylindrical tubes 1102 and 1104 to guide the drill 1120 in order to create overlapping holes in which the spinal fusion implants 220' may be inserted. Further, the removal of disc and bone may be accomplished by the use of a burr, or a chisel of appropriate shape for that purpose and with or without the use of a drill. Once the disc space D' has been drilled, an implant driver instrument is used to insert the spinal fusion implants 220' preferably by linear advancement. The implant driver instrument may be used to either insert or to remove the spinal fusion implants 220'.--

Please replace paragraph 1 on page numbered 23 with the following amended paragraph:

-- The method for the insertion of the spinal fusion implants of the present invention from the posterior aspect of the spine is described in detail in ~~co-pending patent application Ser. No. 08/396,414~~U.S. Patent No. 6,080,155 and is incorporated herein by reference. Further, in the method of inserting the implants of the present invention from the posterior aspect of the spine, it is possible to place the adjacent vertebrae in lordosis prior to the bone removal step.